Proposed Maximum Residue Limit PMRL2013-79

Spirotetramat

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6604-E2
Ottawa, Ontario K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada

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Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) has concluded that the addition of new uses on various fruits and vegetables to the product label of Movento 240 SC Insecticide, containing technical grade spirotetramat, are acceptable. The specific uses approved in Canada are detailed on the label of Movento 240 SC Insecticide, *Pest Control Products Act* Registration Number 28953.

The evaluation of these spirotetramat applications indicated that the end-use product has merit and value, and the human health and environmental risks associated with the new uses are acceptable.

Before registering a pesticide for food use in Canada, the PMRA must determine the quantity of residues that are likely to remain in or on the food when the pesticide is used according to label directions and that such residues will not be a concern to human health. This quantity is then legally established as a maximum residue limit (MRL). An MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except where separate MRLs are specified for the raw agricultural commodity and a processed product made from it.

In addition, the PMRA is proposing to establish MRLs for spirotetramat on various fruits and vegetables to permit the import and sale of food containing such residues. The PMRA has determined the quantity of residues that are likely to remain in or on the imported commodities when spirotetramat is used according to label directions in the exporting country, and that such residues will not be a concern to human health.

Consultation on the proposed MRLs for spirotetramat is being conducted via this document (see Next Steps, the last section of this document). A summary of the field trial data used to support the proposed MRLs can be found in Appendix I.

To comply with Canada's international trade obligations, consultation on the proposed MRLs is also being conducted internationally by notifying the World Trade Organization, as coordinated by the Standards Council of Canada.

The proposed MRLs, to replace or be added to the MRLs already established for spirotetramat, are as follows.

Table 1 Proposed Maximum Residue Limits for Spirotetramat

Common Name	Residue Definition	MRL (ppm)	Food Commodity
Spirotetramat	BYI08330: *cis*-3-(2,5-dimethylphenyl)-8-methoxy-2-oxo-1-azaspiro[4.5]dec-3-en-4-yl ethyl carbonate, including the metabolites BYI08330-enol: *cis*-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one BYI08830-ketohydroxy: *cis*-3-(2,5-dimethylphenyl)-3-hydroxy-8-methoxy-1-azaspiro[4.5]decane-2,4-dione BYI08330-enol-Glc: *cis*-3-(2,5-dimethylphenyl)-8-methoxy-2-oxo-1-azaspiro[4.5]dec-3-en-4-yl β-D-glucopyranoside and BYI08330-monohydroxy: *cis*-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]decan-2-one calculated as parent equivalent	9.0 4.0 3.0[a] 2.5 2.0 1.5 0.8[b] 0.7 0.6 0.5 0.3 0.2	Taro leaves Bananas; plantains Bushberry Subgroup (Crop Subgroup 13-07B) Fruiting Vegetables (Crop Group 8-09) Watercress Globe artichokes; sweet corn kernels plus cobs with husks removed Bulb Vegetables (Crop Group 3-07) Pome Fruit (Crop Group 11-09) Citrus Fruit (Revised Crop Group 10) Instant coffee; pomegranates Low growing berry, except strawberry subgroup (Crop Subgroup 13-07H), except lowbush blueberries and lingonberries; pineapples Green coffee beans

Common Name	Residue Definition	MRL (ppm)	Food Commodity
	BYI08330: *cis*-3-(2,5-dimethylphenyl)-8-methoxy-2-oxo-1-azaspiro[4.5]dec-3-en-4-yl ethyl carbonate, including the metabolite BYI08330-enol: *cis*-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one calculated as parent equivalent	0.08[c]	Meat byproducts of cattle, goats, horses, and sheep

ppm = parts per million

[a] The MRL is proposed to replace the currently established 1.3 ppm MRL for gooseberries, which belong to this crop subgroup.

[b] The MRL is proposed to replace the currently established 0.3 ppm MRL for dry bulb onions, which belong to this crop group.

[c] The MRL is proposed to replace the currently established 0.02 ppm MRL for meat byproducts of cattle, goats, horses, and sheep.

MRLs are proposed for each commodity included in the listed crop groupings in accordance with the Residue Chemistry Crop Groups webpage in the Pesticides and Pest Management section of Health Canada's website.

MRLs established in Canada may be found using the Maximum Residue Limit Database on the Maximum Residue Limits for Pesticides webpage. The database allows users to search for established MRLs, regulated under the *Pest Control Products Act*, both for pesticides or for food commodities.

International Situation and Trade Implications

MRLs may vary from one country to another for a number of reasons, including differences in pesticide use patterns and the locations of the field crop trials used to generate residue chemistry data. For livestock commodities, differences in MRLs can also be due to different livestock feed items and practices.

Table 2 compares the MRLs proposed for spirotetramat in Canada with corresponding American tolerances and Codex MRLs.[1] American tolerances are listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. A listing of established Codex MRLs is available on the Codex Alimentarius Pesticide Residues in Food website, by pesticide or commodity.

[1] The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

Table 2 Comparison of Canadian MRLs, American Tolerances and Codex MRLs (where different)

Food Commodity	Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)
Fruiting Vegetables (Crop Group 8-09)	2.5	2.5	1.0 (Fruiting vegetables other than cucurbits); 2.0 (Peppers chili); 15 (Peppers, chili, dried)
Watercress	2.0	2.0	Not established
Bulb Vegetables (Crop Group 3-07)	0.8	0.8	0.4 (Onion, bulb)
Citrus Fruit (Revised Crop Group 10)	0.6	0.6	0.5
Meat by-products of cattle, goats, horses, and sheep	0.08	0.2 (Meat byproducts of cattle, goat, horse, and sheep)	1.0 (Edible offal [mammalian])

Next Steps

The PMRA invites the public to submit written comments on the proposed MRLs for spirotetramat up to 75 days from the date of publication of this document. Please forward your comments to Publications (see the contact information on the cover page of this document). The PMRA will consider all comments received before making a final decision on the proposed MRLs. Comments received will be addressed in a separate document linked to this PMRL. The established MRLs will be legally in effect as of the date that they are entered into the Maximum Residue Limit Database.

Appendix I

Summary of Field Trial Data Used to Support the Proposed MRLs

Residue data from field trials conducted in Canada and the United States were submitted to support the domestic use of Movento 240 SC Insecticide on various fruits and vegetables. To support the import MRLs on various fruits and vegetables, residue data from supervised residue trials conducted in the United States were assessed. Spirotetramat was applied to fruits and vegetables, which were harvested according to label directions. In addition, processing studies in treated coffee and pineapple were reviewed to determine the potential for concentration of residues of spirotetramat into processed commodities.

Maximum Residue Limits

The recommendation for maximum residue limits (MRLs) for spirotetramat was based upon the submitted field trial data, and the guidance provided in the OECD MRL Calculator. Table A1 summarizes the residue data used to calculate the proposed MRLs for various fruits and vegetables.

Table A1 Summary of Field Trial and Processing Data Used to Support Maximum Residue Limits

Commodity	Application Method/ Total Application Rate (g a.i./ha)	PHI (days)	Residues (ppm)		Concentration Factor
			Min	Max	
Dry bulb onions	Foliar/ 174–186	2–4	<0.054	<0.34	Not applicable
Green onions	Foliar/ 181–183	6–7	<0.15	<0.34	
Highbush blueberries	Foliar/ 522–557	6–7	<0.40	<1.6	
Lowbush blueberries	Foliar/ 522–526	7–8	<0.38	<1.2	
Cranberries	Foliar/ 518–548	7–8	<0.05	<0.15	
Sweet corn kernels plus cobs with husks removed	Foliar/ 250–278	6–8	<0.061	<0.75	
Globe artichokes	Foliar/ 555–563	2–3	<0.22	<0.75	
Watercress	Foliar & Chemigation/ 425–443	3	<0.29	<0.71	

Commodity	Application Method/	PHI	Residues (ppm)		Concentration
Coffee	Foliar/ 536–555	13–14	<0.05	0.0079	4.4X (instant coffee)
Pineapple	Foliar/ 351–359	1	<0.053	<0.111	0.7X (juice)
Banana	Foliar/ 1400–1450	1	<0.51	<2.1	Not applicable
Pomegranate	Foliar/ 349–356	1	<0.070	<0.199	

PHI = preharvest interval; ppm = parts per million

Based on the dietary burden and residue data, MRLs of 0.08 ppm in meat byproducts of cattle, goats, horses, and sheep to cover spirotetramat and its metabolite BYI08330-enol (expressed as parent equivalents) are also proposed.

Following the review of all available data, MRLs as indicated in Table 1 are recommended to cover residues of spirotetramat in various fruits and vegetables. Residues of spirotetramat in these commodities at the proposed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.